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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/062,467

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Andrew C. Hiatt

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04/27/2005

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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/062,467

Applicant(s)

HIATT ET AL.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 January 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

An amendment of 1/28/05 canceled claim 1, amended claims 2, 4 and 5, and added new claims 7-12.

Claims examined on the merits are 2-12, which are all claims in  
5 the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 8 is objected to because of the following informalities:  
part of the last line has been lined through. It is uncertain as to  
10 the purpose of lining through a portion of the line since the claim is new and not amended. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

Claims 2-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The  
15 claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Adequate support is not found in the specification for the  
20 targeting molecule not containing at least one domain selected from the group consisting of C<sub>H1</sub>α, C<sub>H2</sub>α, C<sub>H3</sub>α and C<sub>L</sub> domains. At page 8, lines 8-12, the specification supports the targeting molecule not containing an I<sub>g</sub>A heavy chain containing C<sub>H1</sub>α, C<sub>H2</sub>α and C<sub>H3</sub>α domains and an I<sub>g</sub>A light chain containing a C<sub>L</sub> domain. The specification does not

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support selecting any one of the C<sub>H</sub>1 $\alpha$ , C<sub>H</sub>2 $\alpha$ , C<sub>H</sub>3 $\alpha$  and C<sub>L</sub> domains or any combination thereof as being not present. It is suggested claim 2 be amended by canceling all of the claim after "contain" in line 7 and inserting --- an I<sub>g</sub>A heavy chain containing C<sub>H</sub>1 $\alpha$ , C<sub>H</sub>2 $\alpha$  and C<sub>H</sub>3 $\alpha$  domains  
5 and an I<sub>g</sub>A light chain containing a C<sub>L</sub> domain ---. This type of change should also be made to claims 4, 5 and 8.

The specification further fails to recite "basolateral epithelial surface" (bridging lines 1 and 2 of claim 12), and does not support this term. The specification supports a basolateral factor attached  
10 to a basolateral domain of an epithelial cell surface. For example, see page 5, lines 6-17. It is suggested that claim 12 be amended after "basolateral" in line 1 by inserting --- factor attached to a basolateral domain of an ---, in line 2 after "epithelial" inserting -  
-- cell ---.

15 ***Claim Rejections - 35 USC § 112***

Claims 2 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20 In line 6 of claim 2, "or surface" is unclear as to what contains the surface. It appears the surface should be that of an epithelial cell, and this should be made clear by inserting --- epithelial cell -  
-- before "surface".

In claim 12, the meaning and scope of "basolateral epithelial surface" is uncertain. The relationship between basolateral and epithelial and surface is unclear. The amendment suggested above to claim 12 will overcome this indefiniteness.

***Double Patenting***

Claims 2-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,391,280 B1 or claims 1-37 of U.S. Patent No. 6,045,774. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed targeting molecule and targeting molecule linked to an imaging agent would have been obvious from the targeting molecule linked to an imaging agent claimed by the claims of the patents.

***Response to Arguments***

Applicants state that a terminal disclaimer will be filed when notified of allowable subject matter.

***Conclusion***

The claims are free of the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date

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of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be  
5 calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff  
10 whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this  
15 application or proceeding is assigned is 751-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
Art Unit 1651

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DMN  
4/22/05